

REMARKS

Summary

Claims 1, 26-32, and 34-45 are pending. Claim 33 is cancelled, claims 1, 30-32, and 34-37 are amended, and claims 38-45 are added. No new matter is added.

Allowable Subject Matter

Applicants thank the examiner for the indication that claim 37 would be allowable if rewritten to overcome the 35 USC 112, first paragraph, rejection. Accordingly, claim 37 has been amended herein to clarify the meaning of the claim and to comply with the written description requirement.

Claim Objections

Claims 1, 30, 31, and 34-36 are objected to for various informalities. The claims have been amended herein to correct the identified language.

112 Rejection of Claim 37

Claim 37 is rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The objectionable language in claim 37 has been amended herein to clarify the meaning of the claim and to comply with the written description requirement. Thus, Applicants respectfully request reconsideration and withdrawal of the rejection.

102(b) Rejections of Claims 1, 2, 26, and 32

Claims 1, 2, 26, and 32 are rejected under 35 USC 102(b) as being unpatentable over US Patent No. 5,820,622 to Gross et al. (Gross). Applicants respectfully traverse the rejection in light of the amendments to the claims and the remarks below.

Claims 1 and 32, recite in part a method of measuring an analyte concentration comprising providing an analyte sensing element having an indicating electrode

covered by an absorbent layer forming an exterior surface of said analyte sensing element; and introducing said analyte sensing element into soft tissue of said animal body, thereby placing said absorbent layer into contact with said animal body soft tissue and said body fluid, and removing the analyte sensing element prior to activating the analyte sensing element.

Gross is cited for teaching a method of measuring an analyte concentration in a body fluid, but fails to teach, at least, removing the sensing element prior to activation of the sensing element for measurement purposes. The Office Action indicates that removal of the electrode is inherent, since the electrodes may be replaced. However, claims 1 and 32, recite not only removal, but removal prior to activation of the sensing element. This distinction is not taught by Gross.

The configuration of the sensing element and the operations recited in claims 1 and 32 provide for a method in which the sensing element may be introduced into an animal body, and then removed for measurement purposes. Such a method allows for the measurement operations to occur outside the body, limiting the time the sensing element is indwelling and thus limiting user/patient discomfort.

Therefore, Gross fails to teach at least one element of claims 1 and 32, and thus claims 1 and 32 are patentable over Gross. Applicants thus respectfully request reconsideration and withdrawal of the rejection.

Claims 2 and 26 are dependent on claim 1 incorporating its features, and thus claims 2 and 26 are patentable over Gross for at least the reasons discussed above.

The feature of removing the sensing element prior to activation was rejected over US Patent Application No. 2003/0223906 to McAllister et al. (McAllister) in the Office Action with respect to Claim 33, which is now cancelled and incorporated into claim 32.

As cited, in Paragraph 65, McAllister provides:

“Once meter 6 senses that the reaction zone or matrix area is completely filled with the sample of body fluid, the meter electronics or optics are activated to perform analysis of the extracted sample. At this point, the meter may be removed by the patient from the penetration site or kept on the skin surface until the test results are

shown on the display. Meter 6 may alternatively or additionally include means for automatically retracting the microneedle strip from the skin once the reaction cell is filled with the body fluid sample.”

Thus, the first two sentences of Paragraph 65 clearly indicate that a sample is obtained, then the electronics or optics are activated, and then the meter is removed by the patient. Clearly this refers to removal of the meter after activation of the device. The final sentence of Paragraph 65 does little to change the order in the prior statements, but rather, provides for a different mechanism of removing the device (i.e., an automatic retraction means). There is no teaching in Paragraph 65 of introducing an analyte sensing element into a body to obtain a sample and removing the analyte sensing element prior to activating the device. As stated above, such a method allows for the measurement operations to occur outside the body, limiting the time the sensing element is indwelling and thus limiting user/patient discomfort. The limited language of Paragraph 65 of McAllister cannot be fairly interpreted to assert such a teaching.

Therefore, McAllister also fails to teach at least one element of claims 1 and 32, and thus claims 1 and 32 are patentable over McAllister. Thus, taken alone or in combination, claims 1 and 32 are patentable over Gross and McAllister.

103(a) Rejections of Claims 27-29

Claim 27 is rejected under 35 USC 103(a) as being unpatentable over Gross in view of US Patent No. 4,953,552 to DeMarzo (DeMarzo). Claims 28-29 are rejected under 35 USC 103(a) as being unpatentable over Gross in view of US Patent No. 6,083,710 to Heller (Heller).

Claims 27-29 depend directly on claim 1, incorporating the features of claim 1. Therefore, as claim 1 is patentable over Gross, so are claims 27-29, by virtue of at least their dependency. Since DeMarzo and/or Heller do not remedy the above discussed deficiencies of Gross, claims 27-29 are patentable over Gross alone or in combination with DeMarzo or Heller.

103(a) Rejections of Claims 1 and 30-36

Claims 1 and 30-36 are rejected under 35 USC 103(a) as being unpatentable over Gross in view of McAllister. Applicants have addressed the patentability of claims 1 and 32 over Gross and McAllister above. Thus, for at least the reasons previously discussed, Applicants assert that claims 1 and 32 are patentable over the combination of Gross and McAllister.


Claims 30-31 and 34-36 depend on claims 1 or 32, incorporating their features respectively. Therefore, as claims 1 and 32 are patentable over Gross and McAllister, so are claims 30-31 and 34-36, by virtue of at least their dependency.

Conclusion

In view of the foregoing, Applicant respectfully submits that claims 1, 26-32, and 34-45 are in condition for allowance, and early issuance of the Notice of Allowance is respectfully requested.

If the Examiner has any questions, he is invited to contact the undersigned at (503) 796-2844. Please charge any shortages and credit any overages to Deposit Account No. 500393.

Respectfully submitted,
SCHWABE, WILLIAMSON & WYATT, P.C.


Steven J. Prewitt
Registration No. 45,023

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Pacwest Center, Suite 1900
1211 SW Fifth Avenue
Portland, Oregon 97204
Telephone: 503-222-9981